



The Court then set forth the discovery to be completed in the initial pool of cases, including the exchange of Plaintiff and Defendant Fact Sheets. *Id.* at ¶ 3(b). The Court further ordered that the parties may serve up to two sets of “Master Written Discovery” for each product line and may serve case-specific written discovery in the cases selected for individual discovery. *Id.* at ¶ 5(c).

The discovery protocol established in MDL 2187 (*In re Bard*)—and ordered to be followed in this MDL—have been casually and improvidently cast aside by Defendants. Defendants have instead decided to take matters into their own hands and unilaterally establish an individual discovery protocol that is more to their liking. Putting aside their motives for doing so, the fact remains that PTO No. 8 does not authorize written discovery to be served on every individual Plaintiff in MDL 2187 (*In re Bard*); thus, they may not be served in this MDL either. Instead, the parties are only authorized to serve “Master Written Discovery” and case specific discovery on the cases selected for the bellwether trial pool. Defendants’ RFAs do not specifically denote (or by implication infer) that they constitute Master Written Discovery—a fact confirmed by Defendants’ counsel during the meet and confer process.<sup>1</sup> Thus, any claim to the contrary is contrived.

Pretrial Order No. 4 entered in this MDL and Pretrial Order No. 8 entered in MDL 2187 (*In re Bard*) make clear that Defendants are not authorized to serve written discovery on every

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<sup>1</sup> During the meet and confer session, Plaintiffs’ counsel specifically asked Defendants’ counsel if these RFAs were considered “Master Written Discovery” as that term is used in PTO No. 8, and she specifically stated they were not. That response makes sense, particularly given that the RFAs do not on their face claim to be “Master Written Discovery.” Apparently, however, Defendants have changed their mind on this issue in the last few days. Now, in their Motion, Defendants take the position that, even if they are not allowed to serve individual discovery on every Plaintiff in this MDL 2327 (*In re Ethicon*) under the PTOs, they may propound Master Written Discovery and “these RFAs otherwise qualify as one of those master sets.” Motion, at p. 5. Defendants cannot have it both ways.

individual Plaintiff in the MDLs. For these reasons, Plaintiffs have no obligation to respond to the RFAs and their objections on these grounds should be sustained.

Of course, Plaintiffs stand ready to work with Defendants to use the orders and discovery protocols developed and entered by Judge Stanley in MDL 2187 to “devise proposed approaches to discovery which will accomplish discovery of the material facts in an efficient and economical manner” as urged by this Court. But it is unconscionable to allow Defendants to hijack the discovery process and single-handedly expand the scope of discovery in a manner that is patently inconsistent with this Court’s Pretrial Orders.

In addition to violating Pretrial Orders, the RFAs served upon Plaintiffs are otherwise objectionable for the reasons set forth below.

**B. Answering a request to admit by stating in detail why the responding party cannot truthfully admit or deny the request is specifically permitted by Rule 36(a).**

Rule 36(a)(4) provides: “If a matter is not admitted, the answer must specifically deny it *or state in detail why the answering party cannot truthfully admit or deny.*” Fed. R. Civ. P. 36(a) (emphasis added). In responding to requests to admit that various documents constitute “genuine” copies, Plaintiffs state in detail why each request cannot be truthfully admitted or denied—that is, because they have never examined the genuine originals of the documents referenced. This response is plainly sufficient under Rule 36(a).

In fact, RFA responses virtually identical to this were the subject of a detailed legal analysis in *Underhill v. Coleman Co.*, 2012 U.S. Dist. LEXIS 144798 (S.D. Ill. Oct. 5, 2012). In *Underhill*, the requesting party asked the responding party to admit that an attached exhibit was a “genuine copy.” *Id.* at 2. The responding party answered that it could not admit or deny the

truthfulness of records “it has never seen and never had control over.” *Id.* at 4. In finding this answer *sufficient* under the rules, the court stated:

Rule 36(a)(4) specifically states that a party may answer a request to admit by stating in detail why the responding party cannot truthfully admit or deny the request. Defendant’s answers state in detail why each request cannot be truthfully admitted or denied. Plaintiffs are correct to point out that the rule specifies that if a party states its lack of knowledge or information as a basis for its failure to admit or deny, that party is required to state that it made reasonable inquiry and that the information the party does have is insufficient to enable it to admit or deny the request. None of Defendant’s responses, however, assert lack of knowledge or information as a reason for its inability to admit or deny the requests. Without such an assertion, the rule does not require a responding party to state it made a reasonable inquiry and the information it does know is insufficient to admit or deny the request. Accordingly, the Court finds that Defendant’s responses were sufficient under the rules.

*Id.* at 6-7 (emphasis added). Based on the plain language of the rule, Plaintiffs’ response is appropriate.

Defendants’ reliance on *Tustin v. Motorists Ins.*, 2009 U.S. Dist. LEXIS 95947 (N.D. W.Va. Oct. 14, 2009) is misplaced. Unlike the present case, the responding party in *Tustin* did not respond that it could not truthfully admit or deny the request. Instead, the responding party answered that it was not in the possession of the originals, *but then went on to admit* that the exhibits “appear” to be copies of documents it had received during discovery. *Id.* at 7. The court found this response was “essentially a qualified answer” that required the responding party to have made a good faith inquiry into the authenticity of the documents. *Id.*

Unlike in *Tustin*, Plaintiffs do not assert lack of knowledge or information as a reason for their inability to admit or deny the request, so the provision requiring “reasonable inquiry” has no application. Neither do Plaintiffs admit that the documents appear to be similar copies as was the case in *Tustin*—nor could they since they have never seen the original documents at issue. Instead, Plaintiffs simply answer in a manner that is specifically authorized under the rule. *See*

*Underhill*, 2012 U.S. Dist. LEXIS 144798, at 7-8. Defendants have failed to cite any case holding that a response which complies with the specific requirements of Rule 36(a) may nonetheless be deemed insufficient or admitted. Plaintiffs' objection should be sustained.

**C. RFAs that ask a party to ratify legal conclusions and seek admissions regarding conclusions that can be obtained from some more convenient source are objectionable.**

While Rule 36 allows for requests applying law to fact, it is inappropriate for a party to “demand that the opposing party ratify legal conclusions that the requesting party has simply attached to operative facts.” *Disability Rights Council v. Wash. Metro Area*, 234 F.R.D. 1, 3 (D.D.C. 2006) (citing, *inter alia*, *English v. Cowell*, 117 F.R.D. 132, 135 (C.D. Ill. 1986)). Neither is it appropriate to ask the opposing party to admit to facts of which he or she has no special knowledge. *Id.* As stated in *Disability Rights*, RFAs should not be used to ask the party to admit facts of which he or she has no specialized knowledge that would enable them to answer the request with any more certainty than the defendant or the court through judicial notice. *Id.* See also *Tuvalu v. Woodford*, 2006 U.S. Dist. LEXIS 80642, at 19 (E.D. Cal. Nov. 2, 2006) (“[R]equests for admission should not be used ... to ask the party to admit facts of which he or she has no special knowledge.”) (citing *Disability Rights Council*, 234 F.R.D. at 3)).

Despite these legal standards, dozens of RFAs essentially ask unsophisticated Plaintiffs to do just that—to admit to facts about which they have no special knowledge. Request nos. 4, 9 and 85 are illustrate the pure impropriety of the requests as a whole:

RFA No. 4. Admit that on April 16, 1969, the FDA approved Prolene sutures as “safe and effective for use as recommended in the submitted labeling.”

RFA N. 9. Admit that the FDA approved Supplemental NDA #16-374/S-001 on May 8, 1970.

RFA No. 85. Admit that from 1969 until the passage of the 1976 Medical Device Amendments, the FDA regulated Prolene polypropylene monofilament sutures as a drug.

These RFAs are absurd. How can the average Plaintiff be expected to know whether from 1969 until the passage of the 1976 Medical Device Amendments, the FDA regulated Prolene polypropylene monofilament sutures as a drug? While these may be fair “true or false” questions on a law school exam on food and drug law, they are not fair requests for admissions. *See English*, 117 F.R.D. at 135 (finding improper a request that “asks [the party] to admit to what the Court obviously has judicial notice of. It is absurd to require [the party] to admit to the existence of a whole body of federal law.”).

These type of requests also run afoul of Rule 26(b)(2), which govern Rule 36 requests for admissions. Under Rule 26(b)(2), courts are required to limit discovery if “the discovery sought is . . . obtainable from some other source that is more convenient, less burdensome, or less expensive.” Fed. R. Civ. P. 26(b)(2)(C)(i). As noted, the truth (or falsity) of the legal conclusions identified in the aforementioned requests can certainly be established from a more convenient source (e.g., through judicial notice). It is inappropriate to request such information from unsophisticated Plaintiffs. *See Vons Cos. v. United States*, 51 Fed. Cl. 1, 14 (Fed. Cl. 2001) (finding inappropriate request for admission to confirm the genuineness of excerpts from public law and a portion of a Conference Committee Report on basis that “[t]hese are publicly-available legal documents about which defendant has no special knowledge and of which this court can take judicial notice. As such, these requests are inappropriate as ‘obtainable from some other source that is more convenient, less burdensome, or less expensive.’ RCFC 26(b)(1).”) (citing *English*, 117 F.R.D. at 135). Accordingly, Plaintiffs’ objection should be sustained.

#### **D. RFAs that are broad and non-specific violate Rule 36.**

A request that seeks an admission of a party’s “knowledge” of various laws or regulations is objectionable as overbroad and non-specific if phrased in a way that it cannot be admitted or

denied without explanation. *McCarthy v. Darman*, 2008 U.S. Dist. LEXIS 47549, at 6 (E.D. Pa. June 16, 2008) (“Rule 36 should not be used unless the statement of fact sought to be admitted is phrased so that it can be admitted or denied without explanation.”).

Several of the RFAs at issue ask Plaintiffs to admit its knowledge of the fact that the FDA “approved” Supplemental New Drug Applications (SNDAs) or “cleared” various regulatory submissions on certain dates.<sup>2</sup> Neither the FDA approval documents nor the FDA clearance documents from which the admissions are sought are attached to the RFAs. Apart from the fact that Plaintiffs have no special knowledge that would enable them to answer such requests with any more certainty than Defendants or the court through judicial notice, *Disability Rights*, 234 F.R.D. at 6, these RFAs cannot be answered with a yes or no response. Each of these RFAs would require an explanation pointing to the various regulatory provisions and conditions, restrictions or limitations under which the approval or clearance occurred. *McCarthy*, 2008 U.S. Dist. LEXIS 47549, at 6 (“Rule 36 should not be used unless the statement of fact sought to be admitted is phrased so that it can be admitted or denied without explanation.”). For this reason, these RFAs are improper.

Moreover, there is nothing in these requests that applies law to fact, let alone to the facts of this case. *See SEC v. Micro-Moisture Controls, Inc.*, 21 F.R.D. 164, 166 (S.D.N.Y. 1957) (“ . . . a request to admit should specifically set forth the relevant matters of fact on which an admission of truth is sought.”) (quoting *Kraus v. General Motors Corp.*, 29 F. Supp. 430, 431 (D.N.Y. 1939)). As such, these RFAs represent nothing more than abstract conclusions of law.

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<sup>2</sup> *See, e.g.*, RFA No. 9, which states: “Admit that the FDA approved Supplemental NDA #16-374/S-001 on May 8, 1970.”

*See Desper v. Montgomery County*, 1989 U.S. Dist. LEXIS 5962, at 2 (E.D. Pa. May 31, 1989) (requests stating “‘an individual who has been hospitalized’ for a specific cause ‘is handicapped within the meaning of 29 U.S.C. § 70[6],’” without referring to the plaintiff or defendants, were improper). Indeed, it is hard to image a request to admit that is more divorced from relevant matters of fact than one that simply states: “Admit that the FDA approved Supplemental NDA #16-374/S-001 on May 8, 1970.” Plaintiffs’ objections should be sustained.

**E. RFAs that are capable of more than one interpretation are objectionable as vague and ambiguous.**

A request for admission that is capable of more than one interpretation is properly objectionable as vague and ambiguous. *See Zen Investments, LLC v. Unbreakable Co.*, 2008 U.S. Dist. LEXIS 78684, at 4 (E.D. Pa. Oct. 7, 2008) (“To compel answers to vague and indefinite questions capable of more than one interpretation and which require an explanation thwarts the purposes of Rule 36(a)”). In addition to the other objections raised in response to this request, Request nos. 102, 118 and 128 are vague and ambiguous on their face insofar as they ask Plaintiffs to admit facts regarding “intent” without specifying whose intent is referenced. Defendants may desire to re-draft these requests in a clear and unambiguous manner, but they are clearly objectionable as written. *See id.*

**F. RFAs that incorporate by reference dozens of other documents are unduly burdensome.**

“An attempt to seek admissions to the contents of documents incorporated by reference is improper, except when warranted by exceptional circumstances.” *United States v. Consolidated Edison Co. of New York*, 1988 U.S. Dist. LEXIS 14547, at 5 (E.D. N.Y. Dec. 15, 1998); *see also Sparton Corp. v. United States*, 77 Fed. Cl. 10, 28-29 (Fed. Cl. 2007) (“... incorporation by reference of another document in a request for admission has generally been held



improper.”). This is because “the facts admitted in an answer to a request for admission should be ascertainable merely by examination of the request and of the answer.” *United States v. Chevron U.S.A., Inc.*, 1989 U.S. Dist. LEXIS 10236, at 11 (E.D. Pa. Aug. 29, 1989).

Request no. 7 does not meet this requirement. Instead, it contains 35 separate parts and incorporates by reference dozens of other documents that must be reviewed prior to answering the request. Plaintiffs cannot possibly be expected to respond with a simple admit or deny without undue burden, explanation and/or qualification. *See id.* (sustaining objection to request for admission that referred to a compilation of information prepared by the requesting party which incorporated numerous other documents); *SEC*, 21 F.R.D. at 166 (holding that a request to admit which referenced multi-page affidavits and stock purchase transactions was improper). Furthermore, Defendants have failed to show that any “exceptional circumstances” exist that would justify the general prohibition against incorporating documents by reference in a request for admission. Accordingly, Plaintiffs objections to request no. 7 should be sustained.<sup>3</sup>

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<sup>3</sup> Defendants’ reliance on *Amick v. Ohio Power Co.*, 2013 U.S. Dist. LEXIS 177616 (S.D. W.Va. Dec. 18, 2013) is misplaced. *Amick* does not involve Rule 36 requests, nor does it *require* that undue burden objections be supported by affidavits. *Amick* merely stands for the unremarkable proposition that objections to Rule 26 discovery must be supported by more than conclusory and unsubstantiated allegations. Plaintiffs have met their burden by specifically demonstrating the basis for their claim of undue burden—i.e. the request contains 35 separate parts and incorporates by reference dozens of other documents that must be reviewed prior to answering the request. Furthermore, because this request unduly burdensome on its face, no evidentiary support is needed. *See, e.g., Chevron*, 1989 U.S. Dist. LEXIS 10236, at 12 (undue burden objection sustained without supporting affidavit).

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Respectfully submitted,

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